UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,266	06/09/2006	Michael Chorny	CHOP-101US	1341

23122 7590 05/29/2008

RATNERPRESTIA
P O BOX 980
VALLEY FORGE, PA 19482-0980

EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,266	CHORNY ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *18,37-47 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 19-36, and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on February 18, 2008. New claims 48-51 have been added. Claims 18 and 37-47 have withdrawn previously. Claims 1-51 are currently pending.

2. Newly submitted claim 51 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim is drawn to a non-elected species of the particle composition. Applicant elected the species PDGF, dextran, and a biodegradable polymer matrix.

Since applicant has received an action on the merits for the originally presented invention drawn to the elected species comprising PDGF, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 51 is withdrawn from consideration as being directed to a non-elected invention/species. See 37 CFR 1.142(b) and MPEP § 821.03. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.14. Currently, the generic claim has not been allowed.

3. Claims 1-17, 19-36, and 48-50 are currently under examination.

Withdrawal of Rejections

4. The rejection of claims 12, 13, and 32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn based on the amendment to the claims.

Maintenance of Rejections

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-17, 19-36, and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schacht et al. (U.S. Patent 6,458,386 B1; previously cited).

The rejection was explained in the office action mailed October 16, 2007 and equally applies to the newly added claims 48-50 drawn to a PDGF species recited in the claims.

Response to Remarks

7. Applicant's state that the Schacht patent does not anticipate the claims. Applicant's state the Schacht patent does not teach or suggest such a particle. Applicant's state the instant claims do not recite matrices as described by Schacht. Schacht does not teach or suggest to associate a bioactive agent and a complexing agent. In addition, placing agents into a matrix, for example, as described by Schacht, would not produce the claimed particle complex.

Applicant's arguments filed February 18, 2008 have been fully considered but they are not persuasive. Schacht does disclose the wound dressing fabrication in the form of microparticles. The wound dressing can contain PDGF, and dextran sulfate (see e.g., col. 6, lines

42-col. 7, line 16). The composition, wherein the biopolymer matrix further comprises one or a mixture of two or more of the following compounds: a polysulfated oligo- or polysaccharide or fragments thereof; a biocompatible polyanion which has the capacity to bind heparin-binding growth factors; a proteoglycan containing glycosaminoglycan chains capable of binding to heparin-binding growth factors; a functional analogue of heparin which binds or stabilizes heparin-binding growth factors; a monoclonal or polyclonal antibody or a microprotein wherein said antibody or microprotein has a high and selective affinity for molecular factors that can modulate the wound healing process, and wherein said microprotein can be obtained by phage display; a therapeutically effective amount of a drug; compounds having substantial affinity for the incorporated drug, so as to slow down the release of the drug from the matrix and/or stabilizing the drug. Schacht et al. disclose a controlled or slow release device comprising microparticles of a composition loaded with a drug, which can be injected intravenously, subcutaneously, or intramuscularly. The composition, wherein the polysulfated oligo- or polysaccharide is selected from one or more of the following: heparin, heparin sulfate, chondroitin sulfate, dermatan sulfate, and dextran sulfate. The composition, wherein the drug is selected from the group consisting of an EGF, a FGF, a TGF-.beta., an IGF, a PDGF, and keratinocyte cell lysate (see claims 1, 2, 12, and 19).

Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical

chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 27, 2008

/Anand U Desai, Ph.D./
Patent Examiner, Art Unit 1656